National Cancer Institute Institutional Review Board **AGENDA** (*revised 4/25/14*) **April 28, 2014** 10 CRC/3-1608

- 1. Review of Draft Minutes, April 14, 2014
- 2. Announcements
- 3. Old Business
- 4. New Business
- 5. Problem Report Forms
- 6. Other Expedited Actions
- 7. Continuing Reviews
- **8. Response to Stips**P131467, "Phase I/II Study of the Treatment of Metastatic Cancer that Expresses MAGE-A3 Using Lymphodepleting Conditioning Followed by Infusion of Anti-MAGE-A3 HLA-A*01 Restricted TCR-Gene Engineered Lymphocytes and Aldesleukin" Steve Rosenberg, PI
- 9. Amendment

 10C0052-I, "Phase II Study of Dose-Adjusted EPOCH +/-Rituximab in Adults with
 Untreated Burkitt Lymphoma, c-MYC+ Diffuse Large B-Cell Lymphoma and
 Plasmablastic Lymphoma" Kieron Dunleavy, PI
- **10. Amendment** 10C0174-J, "Related and Unrelated Donor Hematopoietic Stem Cell Transplant for DOCK8 Deficiency" Dennis Hickstein, PI
- 11. Amendment

 13C0009-G, "A Multicenter randomized phase II Study of NPC-1C in Combination with Gemcitabine and nab-Paclitaxel versus Gemcitabine and nab-Paclitaxel alone in Patients with Metastatic or Locally Advanced Pancreatic Cancer Previously Treated with FOLFIRINOX" Tim Greten, PI
- **11. Amendment**11C0073-L, "A Phase I Study of NK Cell Infusion Following Allogeneic Peripheral Blood Stem Cell Transplantation from Related or Matched Unrelated Donors in Pediatric Patients with Hematologic Malignancies" Nirali Shah, PI
- **13. Amendment** 12C0066-F, "Phase I Trial of Oral 5-Fluoro-2'-Deoxycytidine With Oral Tetrahydrouridine in Patients With Advanced Solid Tumors" Jim Doroshow, PI
- **14. Initial Review**P141525, "Phase I Study of Ganetespib and Ziv-Aflibercept in Refractory Gastrointestinal Carcinomas, Non-Squamous Non-Small Cell Lung Carcinomas, Urothelial Carcinomas, and Sarcomas" Shivaani Kummar, PI
- **15. Initial Review** P141526, "A Phase I Clinical Trial of T-cells Targeting B-cell Maturation Antigen for Previously Treated Multiple Myeloma" Jim Kochenderfer, PI